K011173

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of this Premarket Notification, "Abbreviated 510(k)", in compliance with 21 CFR, Part 807, Subpart E, Section 807.92

SUBMITTED BY: imed systems & consulting, LLC
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CONTACT PERSON: Kenneth P. Bonner
"U.S. Agent"
Founder and CEO (imed systems & consulting, LLC)

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OFFICIAL CORRESPONDENT: Mohamed Ahmed Hammady
R&D Manager

DEVICE TRADE NAME: TelePax®

COMMON NAME: TelePax®-DVS, TelePax®-AQS, TelePax®-HyperLink

CLASSIFICATION NAME: Picture Archive and Communication System (PACS)

PREDICATED DEVICE: Applicant Name – Applicare Medical Imaging, B.V.
510(k) Number – K962699
Device Name – RadWorks Medical Imaging Software

Applicant Name – IMPAX Technology, Inc.
510(k) Number – K993532
Device Name – DDS

DEVICE DESCRIPTION:

Introduction: *TelePax*® is a medical imaging software with a number of optional module that may be marketed as software only solution, or combined with standard hardware. *TelePax*® is used to acquire, store, retrieve, transmit, display, manipulate images and demographic information, for diagnostic, review, and referral purposes.

TelePax® software is an open system that runs under the Microsoft® NT™ or 2000 operating system and it can operate on any hardware platform that support and meet any these Microsoft® operating systems.

The TelePax®-DVS is a true multi-modality workstation software that can display any digital image from monochrome modalities (such as CR, CT, MR, Nuclear Medicine, and US) in addition it is capable to display 24-bit true color images from other modalities (such as Endoscopy, Microscopy, Gastroscope, and other color "video" sources)

In PACS, or in a departmental network, TelePax-DVS can perform quesry and retrieve actions in addition to open views on DICOM 3.0 compliant archives or other DICOM 3.0 compliant modalities.

The TelePax®-AQS: is a family of solutions to provide connection to imaging modalities to import or acquire images from. TelePax®-AQS can import images from DICOM compliant sources, video sources including 24-bit true color.

TelePax-AQS can obtain, import, or acquire images and data from various sources including, but not limited to (a) DICOM 3.0 compliant modalities, (b) Video images using frame grabber (c)Conversion of non-DICOM 3.0 digital signals (ACR-NEMA 1.0 or 2.0 proprietary) can be converted, and (d) film digitizers and document scanners, and other TWAIN compliant devices.

The TelePax®-HyperLink is a software that communicate and transmit between any of TelePax stations, to optimize the speed of transmission rates achieved between TelePax systems over standard telephone lines. Self-annealing support is a feature that ensures full compliance over noisy phone lines.

Information from outside department or hospital can be received using teleradiology over the hospital network using conventional telephone lines, ISDN, T1, E1, and ATM lines.

INDICATIONS FOR USE:

TelePax® is intended for use in the acquisition, storage, retrieve, communicate, transmit display, manipulate, review, printing, and transmission of medical images and other patient information over the network via the DICOM standard protocol.

TelePax software may be marketed as a software only, or combined with standard hardware, meanwhile it can be used as a standalone system or in connection with a large system.

TelePax® software has the same indications for use and target populations as the legally marketed predicate devices.

SUNSTANTIAL EQUIVALENCE:

Healthy-IT believes that the image management technology, network capabilities and DICOM standard compliance makes TelePax® substantially equivalent to other products

currently in commercial distribution. Specifically, TelePax® is substantially equivalent to the Applicare Medical Imaging RadWorks Software (K962699) and IMPAX Technology DDS Workstation software. As PACS and teleradiology, these devices all provide a similar range of clinical functionality and have the indications for use.

PERFORMANCE STANDARDS:

No performance standards for PACS systems or components have been issued. TelePax® has been designed to comply with the following voluntary standards: ACR/NEMA Digital Image Communication in Medicine (DICOM) for Netwrok Protocol Transfers; and ISO Joint Photographic Experts Group (JPEG) Image Compression Standard.

GENERAL SAFETY AND EFFECTIVENESS CONCERNS:

The device labeling contains instructions for use and indications of use, for the safe and effective use of the TelePax® software. The acquisition, display, storage and retrieval of information provides a minor level of hazard concern, based on an assessment of minimal patient risk related to the use of a PACS network for storage and recall old patient information and medical images.

SOFTWARE DEVELOPMENT:

Healthy-IT's software development follows documented processes for software design, verification, and validation testing according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance.

CONCLUSIONS:

The 510(k) Premarket Notification for the TelePax® Software (TelePax®-DVS , TelePax®-AQS , TelePax® HyperLink) contains adequate information and a data to enable the FDA/CDRH to determine substantial equivalence to the predicated devices. The design and development of the TelePax® software conforms to relevant FDA standards and is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2001

Healthy Information Technology
c/o Kenneth P. Bonner, CHE, MHA
Founder and CEO
Imed Systems & Consulting, LLC
4715 Trail Court
WESTMINSTER MD 21158

Re: K011173
TelePax®-DVS, TelePax®-AQS &
TelePax®-HyperLink
Dated: April 1, 2001
Received: April 17, 2001
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Bonner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications for Use Statement

510(k) Number : K011173

Device Name : TelePax-DVS , TelePax-AQS & TelePax- HyperLink

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

David C. Ingram

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011173

(Optional Format 3-10-98)

Prescription Use √